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GB2273872 A

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BASIC

P3 P4

X25

Application (19) GB (11) 2 273 872 (13) A

(43) Date of A Publication 06.07.1994

(21) Application No 9226683.2

(22) Date of Filing 22.12.1992

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B05B 5/025, A61K 9/08, A61M 11/00

(52) UK CL (Edition M)

A5B B2 B822 B823 B825

B2F FGB F103

(56) Documents Cited

None

(58) Field of Search

UK CL (Edition L) A5B B2, B2F FGB

INT CL<sup>5</sup> A61K, A61M

ONLINE DATABASE: WPI

'Fig 1'

(54) A method of treating skin

(57) A method of delivering to the skin a composition comprising an amphiphilic material which forms upon contact with moisture exuded by the skin, a water-insoluble liquid crystal phase of greater than one-dimensional periodicity, comprising electrostatically spraying the composition thereon.

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

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SKIN TREATMENT SYSTEM

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FIELD OF THE INVENTION

10 The present invention relates to a system for delivering skin treatment agents directly to the skin. More particularly, the invention relates to methods and apparatus for applying such agents onto the skin using the principle of electrostatic spraying.

15 BACKGROUND OF THE INVENTION

20 Conventional skin treatment products are often liquid or viscous products, for example in the form of lotions or creams, and are traditionally applied by gentle massage or rubbing-in with the fingers. Because of the necessity for relatively large amounts of adjunct material, ie. other than the one or more skin treatment actives which it is desired to deposit, to create an aesthetically acceptable delivery vehicle, these known delivery systems are  
25 relatively elaborate, wasteful of cosmetic raw materials

and have limited efficiency in delivering a desired active to an intended site. Control over applied dose is difficult and limited, and the application of the product itself is often time consuming and messy.

5

Another category of compositions which may be applied to the skin are antiperspirant and deodorant compositions. These are typically in the form of lotions, sticks, aerosol sprays, and creams. These suffer various  
10 negatives in terms of their inefficiency of delivery (in the case of sprays), but also for these types of product there is a need to formulate the product in such a way, and with other compounds, to try to provide the composition with improved sensory properties. Aerosol  
15 antiperspirants or deodorants, in particular propellant driven aerosols, have a tendency to be wasteful and can be sensorily unpleasant on application to the skin.

As a further consequence of the presence in such products  
20 of significant amounts of stabilising ingredients such as surfactants, polymers, preservatives etc, sensory properties may often be poor. Stickiness, greasiness and possibly irritation may be experienced by a user. This may be particularly pronounced where skin is damaged or  
25 diseased, in which circumstances application of a treatment agent in particular by massage or rubbing-in will often especially undesirable.

The skin is in fact a very complex substrate, and has many  
30 important characteristics which must be considered in the design of an optimised system for delivering cosmetic or therapeutic actives thereto. Skin has a multi-faceted surface having both lipophilic and lipophilic character, which for example allows the skin to "breathe" and release

water vapour therefrom, yet function as an effective barrier against water, dirt and other unwanted materials. One particularly notable physical feature of skin is its very rough surface terrain, which creates a problem in  
5 successfully applying a desired skin treatment active with a coverage that is both even and approaching 100%.

One new class of skin treatment compositions which is emerging are amphiphilic materials, in particular  
10 amphiphilic materials which form upon contact with moisture exuded by the body, a water-insoluble liquid crystal phase of greater than one-dimensional periodicity. Such compositions are further described in GB application 91-23979.8, the content of which is incorporated by  
15 reference. In particular with regard to aerosols, the use of aerosols to deliver skin treatment agents is believed to be even less efficient than conventional massage or rubbing-in delivery regimes in the context of percentage and evenness of coverage of the rough skin surface.

20 In a very different technical field, the principle of electrostatic spraying of liquid and solid materials is known. In this technique a formulation to be sprayed is raised to a high electric potential in a spray nozzle, to  
25 cause the formulation to atomise as a spray of electrically charged droplets. Such electrically charged droplets seek the closest earthed object to discharge their electric charge, and this can be arranged to be the desired spray target. Hitherto, electrostatic spraying  
30 techniques have been proposed principally for only large-scale industrial and agricultural applications, especially for delivering reactive materials like paints, adhesives and other surface coatings, as well as large-scale delivery of pesticides and other agricultural or

agrochemical formulations. Examples of disclosures in this field include GB-A-1393333, GB-A-1569707, GB-A2092025, EP-A-029301, EP-A-253539 and WO-A-85/00761, the contents of which disclosures are incorporated herein by  
5 reference.

More recently, there have been a small number of proposals for utilising the known principle of electrostatic spraying for delivering particular materials in specific  
10 applications other than those mentioned above.

EP-A-224352 suggests the use of an electrostatic sprayer for delivering a pharmaceutically active agent to the eye, to replace conventional ocular treatment using eye drops.  
15

Also to be mentioned is US 4776515, which proposes an electrodynamic fine particle negative ion generator adapted to spray various liquids, particularly water, but possibly also alcohol, perfume, ammonia, liquid  
20 medications and surfactants. The object of the disclosed system is to provide an ozone-free mist of negatively ionised liquid particles, (which presupposes that the material to be sprayed is ionizable), and the mist that is produced instantly disperses into an open area in which  
25 the apparatus is operated, eg. a room, so that a far-reaching, uniform aerosol is generated which has particular applicability for large public areas such as hospitals, restaurants and offices. Clearly, this system is unsuitable for small-scale personal use, and in many of  
30 its objects goes directly against the principles upon which a solution to the above mentioned prior art problems must be founded.

SUMMARY OF THE INVENTION

As a result of identifying and appreciating the above prejudices and limitations of the known art, we have now  
5 devised a system which enables the principle of electrostatic spraying to be put to effective use in delivering a certain type of skin treatment agents directly to the skin, such that apparatuses and methods are now provided for such delivery regimes which are  
10 technically efficient, cost effective, safe, have widespread consumer applicability and appeal, and solve or at least ameliorate many, if not all, of the problems associated with the prior art.

15 Accordingly, a first aspect the present invention provides a method of delivering to the skin a composition comprising an amphiphilic material which forms upon contact with moisture exuded by the skin, a water-insoluble liquid crystal phase of greater than one-  
20 dimensional periodicity, comprising electrostatically spraying the composition thereon.

In more detail, the method of this aspect of the invention preferably comprises:

25

(a) providing an apparatus which includes:

30

(i) a reservoir containing a composition comprising an amphiphilic material which, upon contact with moisture exuded by the skin, forms a water-insoluble liquid crystal phase of greater than one-dimensional periodicity;

- (ii) at least one delivery means in communication with the reservoir;
- (iii) a high voltage generator powered from an electricity source; and
- (iv) control means for selectively applying the high voltage from the generator to the or each delivery means; and

- (b) actuating the said control means to electrostatically spray the composition from the or each delivery means directly onto the skin at an intended site.

In a second aspect, the present invention provides an apparatus for delivering to skin a composition comprising an amphiphilic material which forms upon contact with moisture exuded by the skin a water-insoluble liquid crystal phase of greater than one dimensional periodicity, directly to the skin, comprising:

- (a) a reservoir for containing the composition comprising the amphiphilic material which is in an electrostatically sprayable form;
- (b) at least one delivery means in communication with the reservoir;
- (c) a high voltage generator powered from an electricity source;

(d) control means for selectively applying the high voltage from the generator to the or each delivery means to electrostatically spray the composition from the or each delivery means.

5

In a third aspect, the present invention provides, in combination, the apparatus as defined above and an electrostatically sprayable composition consisting of or containing an amphiphilic material which forms upon  
10 contact with moisture exuded by the skin a water-insoluble liquid crystal phase of greater than one dimensional periodicity, deposited directly onto the skin.

In a further aspect of the invention, there is provided a  
15 cloud of charged droplets of a composition comprising an amphiphilic material which forms, upon contact with moisture exuded by the skin a water-insoluble liquid crystal phase of greater than one dimensional periodicity. In a preferred aspect of the invention, this charged cloud  
20 is electrostatically charged.

In a different preferred aspect of the invention, the composition may be an antiperspirant composition, and the amphiphilic material which forms, upon contact with  
25 moisture exuded by the body a water-insoluble liquid crystal of greater than one dimensional periodicity, acts as an antiperspirant active.

As a result of our investigations which have led to the  
30 present invention, we have further found that the use of electrostatic spraying for delivering skin treatment compositions comprising such amphiphilic materials, as compared with the know application regimes, may result in some unexpected and surprising findings as regards the



effect on the profile of the skin terrain. The unique effect of electrostatic spraying on the skin profile following product application can lead to certain additional unexpected advantages associated with this novel technique, particularly with respect to percentage and evenness of coverage of the skin surface during application. This aspect is discussed in further detail below, with reference to the accompanying drawings.

10 DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

As mentioned above, the categories of amphiphilic materials which may be used in compositions for use according to the invention are further described in our co-pending application in GB 9123979.8.

It is to be understood in the context of the invention that "amphiphilic material" may include a mixture of materials, at least one of which is amphiphilic.

20 According to preferred embodiments of the above aspects of the invention where the skin treatment composition is an antiperspirant composition, the antiperspirant composition may be free or substantially free of antiperspirant or deodorant levels of metal salts, especially those metal salts used in the prior art as antiperspirant or deodorant actives.

30 By way of background to the types of amphiphilic material which may be suitable in compositions according to the invention, water and certain organic substances can interact to form different structures of liquid crystal. An example of this teaching is to be found in "Biological Membranes" by D. Chapman, Academic Press New York, 1968,

Chapter 3, the content of which is incorporated herein by reference. Amongst the more defined liquid crystal structures that can be formed are cubic liquid crystal structures, which have a long-range periodicity in three dimensions, and hexagonal structures, which have a long-range periodicity in two dimensions.

As described in GB 9123979.8, it has surprisingly been found that certain amphiphilic substances (an amphiphilic substance by definition herein having both hydrophilic and hydrophobic portions in its structure), or mixtures of amphiphilic substances, when used as antiperspirant actives, have an appropriate relative insolubility in water, but also pass through physical phases on the addition of water in which they form, in their final state, liquid crystal structures of greater than one dimensional periodicity, such as those mentioned above. As such, these materials may be used as antiperspirant actives. Preferably, the amphiphilic material when in its liquid crystal phase of greater than one dimensional periodicity has a solubility in water (or sweat) of less than about 0.1% by weight (at 35°C), more preferably less than about 0.05% by weight.

Conveniently, the structure of the amphiphilic material can be determined by standard x-ray scattering techniques, such as those described in the "Biological Membranes" reference referred to above, and which will indicate the periodicity of any structure.

A preferred category of amphiphilic materials which form compositions according to the invention comprises lipid substances, in particular lipids which may for example be found to occur naturally in the human skin. Some examples

of lipids which form compositions according to the invention are glycerol monooleate, optionally as a mixture with oleic acid, and a mixture of glycerol monolaurate and oleic acid. When the composition according to the  
5 invention comprises a mixture of glycerol monolaurate and oleic acid, preferably the ratio of glyceryl monolaurate to oleic acid is from 3:2 to 4:1.

Other amphiphilic substances which form preferred  
10 compositions according to the invention include surfactants, such as, for example, a mixture of sodium oleate with oleic acid or oleic alcohol, or potassium oleate with oleic acid or oleic alcohol.

15 Another category of amphiphilic substances which form preferred compositions according to the invention are emulsifiers, such as, for example, a mixture of lecithin and oleic acid or oleic alcohol. Particularly preferred compositions for spraying comprise glyceryl monolaurate  
20 isostearyl alcohol, batyl alcohol, and penta oxyethylene stearyl ether/dioxy ethylene oleyl ether.

In forming sprayable compositions according to the invention, it is preferred that compositions comprising  
25 the amphiphilic material also additionally comprise at least 40% of a polar solvent. A preferred polar solvent is ethanol. Additionally, it is highly preferred that the amphiphilic material used in compositions according to the invention is miscible with the polar solvent used.

30 Compositions according to the invention comprising such an amphiphilic material may be used as antiperspirant actives in an antiperspirant composition. When used as such, these compositions may contain other optional ingredients.

Examples of other ingredients which can optionally be present in antiperspirant compositions which are used according to the invention include:

- 5        -    cosmetically acceptable vehicles, such as straight-chain and branched alcohols, for examples ethanol, isopropanol, or isobutanol;
- 10       -    volatile and non-volatile silicones, such as dimethyl cyclosiloxanes, such as DOW CORNING fluids DC 344 and DC 345, or polydimethylsiloxane, having a viscosity in excess of  $5 \text{ mm}^2\text{s}^{-1}$ , for example from 50 to 100  $\text{mm}^2\text{s}^{-1}$ , such as DOW CORNING 200 Fluids (standard viscosities 50-100  $\text{mm}^2\text{s}^{-1}$ );
- 15       -    deodorants, possibly including deodorant levels of metal salts,
- 20       -    deoperfumes, and deodorant compounds which can also act as antimicrobial agents, such as unsaturated fatty acids;
- 25       -    hydrophobic oils, such as liquid paraffin oils;
- inorganic electrolytes, such as sodium chloride and sodium sulphate;
- 30       -    cationic polymers, such as Abil Quat 3272 and Abil Quat 3270, both ex. TH Goldschmidt AG;
- thickeners, such as clays, for example Bentone 38 (trade mark), silicas for example Aerosil 200 (trade mark), and hydroxypropyl celluloses such

as Klucel (trade mark) and other cellulose derivatives conventionally used for thickening purposes;

- 5        - skin feel improvers, such as talc and finely divided polyethylene, an example of which is Acumist B18;
- 10       - gelling agents, such as stearyl alcohol or waxes, for example castor wax;
- humectants, such as polyols, for example glycerol;
- 15       - emollients;
- sunscreens;
- perfumes;
- 20       - preservatives and antioxidants;
- skin benefit agents, such as allantoin;
- 25       - colours;

However, an advantage of methods and compositions according to the invention is that in some circumstances it is possible to reduce or even in some cases eliminate  
30 the need for these additional components.

Examples of compositions according to the invention which comprise amphiphilic materials and which may be electrostatically sprayed include:

<u>Example</u>		<u>% (w/w)</u>			
<u>Component</u>		<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>
5	Glyceryl monooleate	10	25	50	60
	Ethanol	90	75	50	40
10		<u>5</u>	<u>6</u>	<u>7</u>	
	Glyceryl monooleate	10	10	2	
	Volatile silicone (DC245, ex Dow Corning)	50	20	8	
	Ethanol	40	70	90	
15		<u>8</u>	<u>9</u>	<u>10</u>	
	Glyceryl monooleate	30	20	60	
	Ethanol	40	60	30	
	Water	30	20	10	
20		<u>11</u>	<u>12</u>	<u>13</u>	
	Glyceryl monooleate	30	30	30	
	Ethanol	40	40	40	
	Water	29	28	25	
	Zinc phenol sulphonate	1	2	5	

25 Compositions which contain amphiphilic materials may also contain additional skin treatment actives, provided the composition retains its electrostatic sprayability. Suitable skin treatment actives may include:

- 30 1. moisturisers, eg. 2-hydroxyalkanoic acids, and acid-soap complexes thereof, polyols such as glycerol and glycols, 2-pyrrolidone-5-carboxylic acid, and other emollients or humectants;

2. occlusive materials, eg. occlusive oils;
3. sun-protective materials, eg. sunscreens,  
particularly UV-absorbing sunscreens;
- 5 4. after-sun care materials, eg. material for  
treating sunburn;
- 10 5. skin conditioning agents, eg. agents which  
smooth or soften the skin;
- 15 6. skin conditioning agents, eg. artificial tanning  
products such as compositions containing  
dihydroxyacetone (DHA);
7. antibacterial or antifungal materials;
8. insect repellants;
- 20 9. astringent materials, eg. hydrolysable tannins,  
phenolic acids associated with tannins, phenols  
associated with tannins, flavonoid compounds,  
natural extracts providing astringency, organic  
25 astringents and inorganic astringents  
(particularly salts of aluminium, zinc, iron  
(III), copper or silver);
10. skin cleansers and make-up or other cosmetic  
removers;
- 30 11. massage oils;
12. skin nutrients and healing agents;

13. spot and skin blemish treatment materials;
14. skin whiteners and agents for treating  
pigmentation disorders, eg. freckles;
- 5 15. antiseptics and disinfectants;
16. anti-ageing agents, eg. for treating wrinkles or  
preventing development thereof;
- 10 17. agents for treating sensitive skin.

One particular advantage of the products which can be delivered by means of the present invention is that it is possible for at least some of the adjunct components which hitherto have been necessarily included in skin treatment products to act as a vehicle be omitted.

Compositions according to the invention may further include solvents, which may be necessary to solubilise the skin treatment active. Suitable solvents are well known in the art and include for example alcohols or polyols such as ethanol, isopropyl alcohol, propylene glycol, dipropylene glycol, phenyl ethyl alcohol, glycerol, 1,3-butanediol, 1,2-propanediol, isoprene glycol.

A principal characteristic of such electrostatically sprayable materials or compositions which it will usually be necessary to carefully select or adjust as necessary (as discussed further below), is their resistivity. Preferred resistivities fall within the range from about 10 to about  $10^{12}$  ohm cm, more preferably from about  $10^6$  to about  $10^8$  ohm cm.



Generally compositions for application to the skin in accordance with the present invention will be leave-on compositions, so it will be generally preferred to exclude from compositions for application any components which are  
5 disadvantages in that respect and may impart deleterious effects on the skin when applied thereto and left on.

As mentioned above, depending upon the composition or material to be delivered, it may be necessary to adjust  
10 its resistivity by addition of one or more resistivity adjusting materials, examples and suitable amounts of which will be either known to persons skilled in the art, or readily derivable by simple experiment. Suitably, polar substances such as alcohols, eg. ethanol, may be  
15 used to lower the resistivity of a given material or composition, whereas non-polar substances, eg. oils and other hydrophobic materials, may be used to increase its resistivity. Alternative resistivity adjusting materials include charged species such as salts, eg. sodium  
20 chloride, or a salt conventionally used in buffers in personal products or pharmacological formulations.

In addition to resistivity, another parameter of the compositions to be sprayed which it may be necessary to  
25 carefully select and adjust is viscosity.

Materials of a wide range of viscosities may be suitable for use in the present invention, but suitably the viscosity is in the range of from about 0.1 to about 1000  
30 mPas, even more preferably from about 0.1 to about 500 mPas, even more preferably from about 0.5 to about 200 mPas (at 25°C). If desired or as necessary one or more viscosity adjusting agents may be included. Examples of such agents include salts, eg. alkali metal or ammonium

halides, polymers and conventional thickening materials and oils and polar oil thickeners such as cosmetic oils, waxes, glycerides and suitable amphiphiles with melting points of for example  $>20^{\circ}\text{C}$ .

5

For use in the present invention, the hardware and electrical componentry and circuitry may be of any suitable construction and design. The art of electrostatic spraying contains many examples of suitable apparatus which may be used in the present invention and such disclosures of such apparatus or particular features thereof may be applied either singly or in combination to the spray systems of the present invention.

15 Examples of suitable electrostatic spraying hardware include, in addition to those of the prior art references mentioned above, those of the following published references: GB-A-2061769, GB-A-2073052, EP-A-031649, EP-A-243031, EP-A-368494, EP-A-468735 and EP-A-368494, EP-A-468735 and EP-A-468736; the disclosures of all of which are incorporated herein by reference.

25 As will be appreciated by persons skilled in the art, particular constructional features, and design and electrical and other operating parameters of such apparatuses may be selected or adjusted as necessary, in the context of the present invention, in accordance with the desired functioning characteristics, as for example dictated by the composition or material to be sprayed and/or the needs or wishes of a user.

30 Features of the apparatus of the present invention which may be so selected and/or adjusted include for example: voltage generated by the high voltage generator and power

source, electric field strength in or in the region of the product delivery means, flow rate of the product to be sprayed from the reservoir to and out of the delivery means, size and configuration of the delivery means itself and construction and properties of any product feed mechanism utilised between the reservoir and the output of the delivery means.

In preferred embodiments of the invention, preferred voltages generated by the high voltage generator from the power source are in the range of from about 2 to about 20 kilovolts, more preferably from about 5 to about 16 kilovolts. The most suitable voltage for a given system may depend upon the product to be sprayed, as well as other parameters, all of which will generally be selected to give an overall optimised system.

Electric field strengths which are responsible for the spraying action of the electrostatic apparatus will be largely dependent upon the voltage applied. However, field strengths may be controlled or adjusted if necessary, for example by changes in nozzle configuration or geometry and/or the use of field intensifying electrodes, which are well known in the art cited above.

Optimum flow rates of material to be sprayed will generally depend upon the composition of the product itself, eg. upon the concentration of the active ingredient(s) being applied and may be selected appropriately on that basis preferably so as to avoid sensory negatives. Also, as already mentioned with respect to viscosity of the sprayable material, a suitable flow rate may be selected depending upon the particular delivery regime and/or habit or needs of a user. By way

of example, preferred flow rates of compositions for delivery in accordance with embodiments of the invention are in the range of from about 0.01 to about 10 ml/min, more preferably from about 0.1 to about 5 ml/min, most preferably 1 to about 3 ml/min per delivery means.

The size and configuration of the one or more delivery means in the apparatus of the invention may be of any suitable form and again may be selected in association with other parameters to give an optimised functioning electrostatic spray delivery system. Commonly, the or each delivery means will be in the form of a nozzle, preferably of insulating or semi-insulating material such as plastics or various polymers, as is well known in the art.

In one preferred form of nozzle, a conduit for carrying the product to be sprayed terminates in an orifice at the tip of the nozzle, from which orifice the product is ejected for example initially as a ligament but in any event eventually dispersing as a spray of charged droplets. The orifice preferably has a diameter of not greater than about 600 microns, more preferably not greater than about 350 microns. Even more preferably the orifice has a diameter of between about 60 and about 250 microns, most preferably 80-250 microns.

The delivery means may advantageously include metering means to provide a dosing mechanism for delivering a predetermined fixed amount of material from the or each nozzle. Such an expedient may for example be useful in conjunction with a system having a controlled flow rate.

In preferred embodiments of the apparatus of the invention, the or each delivery means is in communication, ie. preferably fluid communication, with the reservoir or reservoirs (if for example more than one material or composition is to be desired to be sprayed from the same apparatus or even the same delivery means) by virtue of product feed means.

In one preferred form, such feed means may comprise a wick, eg. a porous wick, through and/or over which the product to be sprayed flows before reaching the point of high electric field strength where it is dispersed as a charged spray of droplets or particles. In another preferred form the feed means may comprise a hollow conduit through which the composition passes under the effect of capillary action. As a further alternative, in systems which for example require a particularly high flow rate, special feed means may be provided, for example a pump which may usefully be employed with either of the other types of feed means described above. The pump may be of any suitable type, eg. electrically operated, but more conveniently it may be a simple mechanical device which exerts pressure on the reservoir containing the composition to be sprayed, such that the composition therein is forced out of the reservoir to the delivery means.

As is well known in the art, the apparatus according to the invention preferably include a trigger (ie. a manual control means) or alternatively an automatic control means to selectively apply the high voltage from the generator to the or each delivery means to electrostatically spray the benefit or treatment agent onto the skin. Any other suitable control means however, eg. which automatically

control actuation of the system, may be used, as will be appreciated by persons skilled in the art.

5 A particularly preferred embodiment of spray device for use according to the invention is described below, and shown schematically in Figure 1.

10 The spraying apparatus itself is constructed with a similar size, shape and weight to a conventional aerosol spray, so as to form a hand-held unit which is easy to manipulate and use and suitable for personal use. The apparatus comprises an elongate housing 1, which is preferably electrically insulating, eg. of a plastics material, within which the electrical and other hardware  
15 components of the apparatus are mounted.

Towards the base of the apparatus is housed a battery 8, such as a conventional low voltage, eg. 9 volts, cell, which location allows ready access to the battery for the  
20 purpose of replacement when necessary. Indicated by numeral 6 is the high voltage generator, which converts the low voltage from the battery 8 into the high voltage of for example between about 8 and 18 kV, which is required for raising the product to be sprayed to the high  
25 electric potential necessary to effect electrostatic spraying thereof. Suitable components of the high voltage generator 6 are well known in the art and comprise principally a coil or transformer to perform the voltage step-up function. If desired or as necessary, various  
30 packing elements of electrically insulating material, such as that shown as 7 in Figure 1, may be provided in order to increase the safety aspect of the high voltage apparatus and to reduce unwanted leakage paths to earth when the apparatus is in use.

Connected between the battery 8 and high voltage generator 6, as well as between the high voltage generator 6 and the remaining electrical componentry of the apparatus, are one or more circuit boards 12 containing any necessary  
5 auxiliary electrical componentry for ensuring satisfactory functioning of the apparatus. Such additional circuit board(s) 12 may comprise for example DC/AC (or vice versa) converters, as well as voltage adjustment means to control the high voltage applied to the product delivery means  
10 from which the product to be sprayed is to be delivered.

In the upper region of the apparatus is mounted reservoir 2 containing the product to be sprayed which contains a skin treatment agent comprising an amphiphilic material as  
15 previously described, together with one or more additional components as desired, provided the spray characteristics are maintained. In one preferred embodiment, the composition to be sprayed is an antiperspirant composition.

20 In fluid communication, via a conduit 16, with the reservoir 2 is a nozzle 14, which is connected electrically to the high voltage electrics of the apparatus so that the product within the nozzle is raised  
25 to the high electric potential necessary to effect its egress from the nozzle under electrostatic forces, and the electrostatic spraying thereof. The nozzle 14 itself comprises an internal chamber 17 which terminates at the tip of the nozzle in an orifice 18 from which the product  
30 within the chamber 17 emerges under the influence of electrostatic forces. As already described, the orifice 18 most suitably has a diameter of between about 60 and about 250 microns and the flow rate of product emerging therefrom is most preferably in the range of about 1 to 3

ml/min. At these flow rates, it is preferable to have a product feed means to pump product from the reservoir 2 to the nozzle 14 ready for spraying.

5 The configuration of the nozzle 14 in the region of the orifice 18 may vary and may be selected in association with other spraying parameters in order to give an optimised system for a given product to be delivered. For example, the nozzle tip configuration as shown in Figure 1  
10 may be particularly suitable for relatively high resistivity liquids to be sprayed, this configuration generating quite satisfactory fine, wide sprays of such products, eg. between about  $10^6$ -  $10^8$  ohm cm.

15 The apparatus is preferably provided with some kind of cap 30 for protecting the nozzle 14 and other delicate components in the upper region of the apparatus from physical damage or contamination when the apparatus is not in use.

20 Shown schematically in Figure 1 as 11 is a manual trigger which constitutes control means for selectively energising the unit to apply the high voltage to the nozzle to electrostatically spray the product therefrom. The  
25 trigger 11, like the other elements of the apparatus subject to unwanted voltage leakage or shock risk, is preferably constructed and situated to minimise such problems, expedients for which are known in the art.

### 30 Skin surface profilometry studies

Skin surface profilometry may be used to investigate the effects of applying liquid skin treatment compositions to skin in vivo, specifically to compare the effects of



application regimes of the prior art (rub-in and pump spray) and of the present invention (electrostatic spray). Skin surface profilometry techniques and principles are described for example in the following two references, the disclosures of both of which are incorporated herein by reference:

1. "Topographics of dry skin, non-dry skin, and cosmetically treated dry skin as quantified by skin profilometry", T.H. Cook & T.J. Craft; J.Soc. Cosmet. Chem., 36, 143-152 (1985);
2. "Assessment of skin conditions using profilometry", Peter L Dorogi & Marek Zielmiski; Cosmetics & Toiletries, 104, (March 1989).

#### Experimental Protocol

A silicone rubber impression material (SILFLO TM, ex Flexico Developments Ltd.) may be used to obtain negative replicas of the skin surface before and after product application. Replicas are taken from the volar forearm using a maximum of three sites per arm (each sited 4x3 cm). The sites are separated by 2-3 cm and are a minimum of 4 cm distance from the wrist and the mid-arm fold. Each site is equilibrated for 15 min. at 21°C/50% relative humidity before replication.

A SURFCOM 113B profilometer from Advanced Metrology Systems Ltd. may be used to characterise the replica surface. A stylus of 5µm radius is made to traverse horizontally over a specimen surface with a stylus force of 0.4g. The vertical movement of the stylus is measured and accumulated data was converted electronically to give

standard roughness parameters. Measurements can be made at 45 degree intervals of sample rotation and the mean of eight 10mm long trackings can then be calculated.

- 5        Two parameters can be determined:
- the arithmetic mean of vertical variations from a calculated reference line (ie. variation in peaks and valleys relative to a "mean reference line").
  - 10       -        the maximum peak to valley height in the total scan.

Replicas taken before product application can be used as controls. Products can be applied to simulate actual  
15       usage levels. Replicas can then be taken three minutes after product application.

Compositions according to the invention, when sprayed according to the method of the invention, demonstrate good  
20       even coverage of skin.

Claims

1. A method of delivering to the skin a composition comprising an amphiphilic material which forms upon contact with moisture exuded by the skin, a water-insoluble liquid crystal phase of greater than one-dimensional periodicity, comprising electrostatically spraying the composition thereon.
2. An electrostatically sprayable composition comprising an amphiphilic material which forms upon contact with moisture exuded by the skin a water-insoluble liquid crystal phase of greater than one-dimensional periodicity.
3. A cloud of charged droplets comprising an amphiphilic material which forms, upon contact with moisture, a water-insoluble liquid crystal phase of greater than one-dimensional periodicity.

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**Patents Act 1977**  
**Examiner's report to the Comptroller under**  
**Section 17 (The Search Report)**

Application number

GB 922668.2

**Relevant Technical fields**

(i) UK CI (Edition 1 ) A5B (B2); B2F (FGB)

(ii) Int CI (Edition 5 ) A61M, A61K

**Databases (see over)**

(i) UK Patent Office

(ii) ONLINE DATABASE: WPI

**Search Examiner**

S I AHMAD

**Date of Search**

20 April 1993

Documents considered relevant following a search in respect of claims 1-3

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
	NONE	

SF2(p)

ms - doc99\fil001379

94193870

Category	Identity of document and relevant passages - 28 -	Relevant to claim(s)

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**P:** Document published on or after the declared priority date but before the filing date of the present application.

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